

DEPARTMENT OF HEALTH AND HUMAN SERVICES

172 65

Mr. Terry B. Stone
Regulatory Affairs Manager
The Agricultural Group of Monsanto Company
700 Chesterfield Parkway North
Chesterfield, MO 63198

Dear Mr. Stone:

This is in regard to your genetically modified Colorado potato beetle (CPB)-resistant potato about which you initiated consultations with the agency in February 1993. The new potato variety has been rendered resistant to CPB by expression of a pesticidal protein (*B.t.t.* protein, product of the *cryIIIA* gene) from *Bacillus thuringiensis* subspecies *tenebrionis*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new potato variety on August 25, 1994. On September 23, 1994, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by Monsanto to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded that the new potato variety is not materially different in composition, safety, or any other relevant parameter from potato varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0005 and that will be maintained in the Office of Premarket Approval.

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Based on the description of the data and information presented during the consultations, the new potato variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning this product at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247 HFS-013 HFV-221
BNF 0005